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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/050,898 | 01/18/2002 | Wolfgang A. Renner | 1700.0190005/BJD/SJE | 7794 |

26111 7590 12/30/2005

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| EXAMINER | |
|---|---|
| SALVOZA, M FRANCO G | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 10/050,898 | RENNER ET AL. |
| | Examiner | Art Unit |
| | M. Franco Salvoza | 1648 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

After review of the previous restriction, it was determined that upon further consideration that further restriction is appropriate for a thorough and complete examination. The Office regrets any inconvenience. The restriction set forth below replaces the previous one.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 36-38, 40-50, 52 drawn to a composition comprising a non-natural molecular scaffold comprising a core particle wherein selected core particle is a virus, and a recombinant form of it, and a pharmaceutical and vaccine composition comprising it, classified in class 435, subclass 235.1.

II. Claims 1-17, 23-50, 52 drawn to a composition comprising a non-natural molecular scaffold comprising a core particle wherein selected core particle is a virus like particle and a recombinant form of it, and a pharmaceutical and vaccine composition comprising it, classified in class 424 subclass 199.1.

III. Claims 1, 36-38, 40-50, 52 drawn to a composition comprising a non-natural molecular scaffold comprising a core particle wherein selected core particle is a bacteriophage and a recombinant form of it, and a pharmaceutical and vaccine composition comprising it, classified in class 435, subclass 235.1.

IV. Claims 1, 18-22, 28-50, 52 drawn to a composition comprising a non-natural molecular scaffold comprising a core particle is a bacterial pilus and a

recombinant form of it, and a pharmaceutical and vaccine composition comprising it, classified in class 435, subclass 243.

V. Claims 1, 36-38, 40-50, 52 drawn to a composition comprising a non-natural molecular scaffold comprising a core particle wherein selected core particle is a viral capsid particle and a recombinant form of it, and a pharmaceutical and vaccine composition comprising it, classified in class 435, subclass 235.1.

VI. Claim 51, drawn to a method of immunization, classified in class 424, subclass 278.1.

VII. Claim 53, drawn to a process for producing an array, classified in class 435, subclass 317.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions include patentably distinct products as core particles: a virus, a virus-like particle, a phage, a bacterial pilus and a capsid protein. Each of the products has a distinct function, distinct structure, and distinct physical, chemical and functional properties requiring separate searches of the prior art.

Inventions I-V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case methods of immunization can use other compositions other than the one cited. Conversely, the composition as claimed can be used for other materially different processes other than mere administration of the composition for immunization purposes.

Inventions I-V and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made recombinantly by other materially different processes. Conversely the methods of immunization can be performed using materially different products other than the one claimed.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are materially different. Producing a molecular antigen array is a materially different process with different steps and effects than immunizing a subject with the claimed compound.

***Species Election***

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Invention I, II, III, IV or V is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

If Invention I, III or V is chosen, a species must be elected in claims 37, 38, 48 and 49.

If Invention II is chosen, a species must be elected in claims 23, 35, 37, 38, 48 and 49. Furthermore, if the RNA phage (species (l)) in claim 23 is chosen, then one species of RNA phage in claim 25 must be chosen. However, if the species of recombinant proteins of Hepatitis B virus is chosen, claims 11-17 are elected for examination. And if claims 11-17 are elected, then one species of Hepatitis B virus capsid protein must be elected in claim 14.

If Invention IV is chosen, a species must be elected in claims 35, 37, 38, 48 and 49.

Claim 14: Further restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 14:

- the amino acid sequence of SEQ ID NO: 89
- the amino acid sequence of SEQ ID NO: 90
- the amino acid sequence of SEQ ID NO: 93
- the amino acid sequence of SEQ ID NO: 98
- the amino acid sequence of SEQ ID NO: 99
- the amino acid sequence of SEQ ID NO: 102
- the amino acid sequence of SEQ ID NO: 104
- the amino acid sequence of SEQ ID NO: 105
- the amino acid sequence of SEQ ID NO: 106
- the amino acid sequence of SEQ ID NO: 119
- the amino acid sequence of SEQ ID NO: 120
- the amino acid sequence of SEQ ID NO: 123

- the amino acid sequence of SEQ ID NO: 125
- the amino acid sequence of SEQ ID NO: 131
- the amino acid sequence of SEQ ID NO: 132
- the amino acid sequence of SEQ ID NO: 134
- the amino acid sequence of SEQ ID NO: 157
- the amino acid sequence of SEQ ID NO: 158

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq*. (MPEP § 803.04).

Claim 23: Further restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 23:

- Recombinant proteins of Hepatitis B virus
- Recombinant proteins of Measles virus
- Recombinant proteins of Sindbis birus
- Recombinant proteins of Rotavirus
- Recombinant proteins of Foot-and-Mouth-Disease virus
- Recombinant proteins of Retrovirus
- Recombinant proteins of Norwalk virus

- Recombinant proteins of Alphavirus
- Recombinant proteins of Human Papilloma virus
- Recombinant proteins of Polyoma virus
- Recombinant proteins of Bacteriophages
- Recombinant proteins of RNA-phages
- Recombinant proteins of Qβ-phage
- Recombinant proteins of GA-phage
- Recombinant proteins of Fr-phage
- Recombinant proteins of GA-phage
- Recombinant proteins of Ty

The species of recombinant proteins are patentably distinct because the proteins do not share common structure with the other species.

Claim 25: Restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 25:

- Bacteriophage Qβ
- Bacteriophage R17
- Bacteriophage Fr
- Bacteriophage GA
- Bacteriophage SP
- Bacteriophage MS2
- Bacteriophage M11

- Bacteriophage MX1

- Bacteriophage NL95

- Bacteriophage F2

- Bacteriophage PP7

The species of bacteriophages are seen as patentably distinct because none of the species share common structure with the other species.

Claim 35: Restriction to one of the following groups is also required under 35 U.S.C. 121 in Claim 35:

- CGG

- (G)kC(G)n with n=0-12 and k=0-5; (G)kC(G)m(S)t(GGGGS)n with n=0-3, j=0-5, m=0-10, l=0-2;

- GGC; GGC-NH2;

- GnCGk with n=0-12 and k=0-5;

- GmStGGGGSnG0CGk with n=0-3, k=0-5, m=0-10, l=0-2 and o=0-8

- N-terminal gamma 1-linker

- N-terminal gamma 3-linker

- N-terminal glycine linkers

- N-terminal glycine serine linkers

- C-terminal gamma 1-linker

- C-terminal gamma 3-linker

- C-terminal glycine linkers

- C-terminal glycine-serine linkers

- Ig hinge regions

The groups of amino acid linkers are seen as patentably distinct because none of the groups share a common structure with the other groups.

Claim 37: Restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 37:

- SMPH

- Sulfo-MBS

- Sulfo GMBS

The species of heterobifunctional cross-linkers are seen as patentably distinct because the none of the species share a common structure with the other species.

Claim 38: Restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 38:

- The amino acid sequence of DAEFRHDSGYEVHHQGGC

- The amino acid sequence of CGHGNKSGLMVGGVVIA

- The amino acid sequence of

DAEFRHDSGYEVHHQKLVFFAEDVGSNGGC

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the

contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq*. (MPEP §803.04). Since these sequences code for different proteins and independent and distinct inventions, claim 6 is subject to a restriction requirement. While the MPEP §803.04 states that normally at least ten sequences constitute a reasonable number for examination purposes, the Office is moving away from that practice making the claim subject to restriction.

Claim 48: If Group B is chosen, restriction to one of the following species is also required under 35 U.S.C. 121:

- CGG
- (G)kC(G)n with n=0-12 and k=0-5; (G)kC(G)m(S)t(GGGGS)n with n=0-3, j=0-5, m=0-10, l=0-2;
- GGC; GGC-NH2
- GnCGk with n=0-12 and k=0-5
- GmStGGGGSnG0CGk with n=0-3, k=0-5, m=0-10, l=0-2 and o=0-8
- N-terminal gamma 1-linker
- N-terminal gamma 3-linker
- N-terminal glycine linkers
- N-terminal glycine serine linkers
- C-terminal gamma 1-linker
- C-terminal gamma 3-linker
- C-terminal glycine linkers

- C-terminal glycine-serine linkers

- Ig hinge regions

These species of amino acid linkers are seen as patentably distinct because none of the groups share a common structure with the other species.

Claim 49: Restriction to one of the following groups is also required under 35 U.S.C. 121 in Claim 49:

- CGG

- CGKR

- CGHGNKS

- GGC; GGC-NH2

The species of amino acid linkers are seen as patentably distinct because none of the species share a common structure with the other species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent

issues. See MPEP § 804.01.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached at (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Franco Salvoza
Patent Examiner

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12/26/05
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Art Unit 1648